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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/810,788	03/26/2004	Diane M. Ruezinsky	MONS:060US	9881

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FULBRIGHT & JAWORSKI, LLP
600 CONGRESS AVENUE, SUITE 2400
AUSTIN, TX 78745

EXAMINER	
PAGE, BRENT T	

ART UNIT	PAPER NUMBER
1638	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/810,788	RUEZINSKY, DIANE M.	
	Examiner	Art Unit	
	Brent Page	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 October 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13* is/are pending in the application.

4a) Of the above claim(s) *11* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10,12 and 13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *26 March 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *3/14/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Applicant's election without traverse of Group I claims 1-10 and 12-13 and SEQ ID NO: 4 in the reply filed on 10/24/2005 is acknowledged.

Claim 11 is withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected Group, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 10/24/2005.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 1 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claim covers a product of nature because the claim does not require the promoter to be present in a purified or isolated form. The promoter and the polynucleotide sequence comprising the sequence of SEQ ID NO:4 is found in an unpurified and non-isolated form in nature. Since promoter sequence that is isolated or purified is not found in nature, it is suggested that Applicant use such language if appropriate in the claim to further define the invention (MPEP § 2105).

Claim 10 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

The claim is broadly drawn to a seed from a transgenic plant. However, due to Mendelian inheritance of the transgene, some seeds produced by a transgenic plant will not have a copy of the transgene, and will thus be indistinguishable from naturally occurring seeds. Accordingly, the claim is drawn to a product of nature, which is non-statutory subject matter.

See Diamond v. Chakrabarty, 447 U.S. 303 (1980), Funk Bros. Seed Co. V. Kalo inoculant Co., 233 U.S. 127 (1948), and American Fruit Growers v. Brogdex Co., 283 U.S. 2 (1931).

This rejection can be overcome by amendment of claim 10 to indicate that the seed comprises said construct.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-10 and 12-13 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contain subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims are broadly drawn to polynucleotides comprising a multitude of fragments of any length of SEQ ID NO:4, including those fragments as small as a single

base pair, which would function as a promoter. See claim 1, part (b). The claims are also drawn to a multitude of sequence variants of SEQ ID NO:4 with as little as 70% identity thereto, or a multitude of polynucleotides comprising a multitude of sequence variants with as little as 70% identity to any fragment of SEQ ID NO:4, each of which would retain promoter function. See claim 1, part (c). The claims are also broadly drawn to a multitude of transgenic plant cells and plants of any plant species which comprise constructs comprising said sequence fragments or sequence variants, wherein a heterologous coding sequence is expressed therefrom in amounts sufficient to confer an agronomic trait to said plant cells or plants. See claims 2-9.

In contrast, the specification only provides guidance for the isolation of a promoter from *Arabidopsis* comprising the entire SEQ ID NO:4, wherein said promoter functions to express heterologous coding sequences. No guidance is provided in which any particular fragment or particular variant of SEQ ID NO:4 would function as a promoter in the native plant species from which it was isolated, or in any other plant species into which it is introduced.

The function of promoter fragments and sequence variants in transgenic plants is unpredictable. Kim et al (1994, Plant Molecular Biology 24:105-117) in a mutational analysis of the nopaline synthase promoter in a stable transformation system, found that mutation of a single nucleotide significantly altered the strength of expression, while deletions in other regions of the promoter completely eliminated function (page 108 first full paragraph).

Furthermore, the function of promoter fragments and sequence variants in transgenic plants is unpredictable wherein the promoter function is regulated by conditional elements. Dolferus et al (1994, Plant Physiology 105:1075-1087) in a deletion analysis of the *Arabidopsis Adh* promoter, found that deletion of different elements of the promoter affected promoter function conditional to the stress that was applied to the given promoter fragment (page 1080, last full paragraph and page 1082 first full paragraph).

Given the claim breadth, unpredictability, and lack of guidance as discussed above, undue experimentation would have been required by one skilled in the art to develop and evaluate fragments and variants of SEQ ID NO:4 that retain promoter function.

Claims 1-10 and 12-13 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are broadly drawn to polynucleotides comprising a multitude of fragments of any length of SEQ ID NO:4, including those fragments as small as a single base pair, which would function as a promoter. See claim 1, part (b). The claims are also drawn to a multitude of sequence variants of SEQ ID NO:4 with as little as 70% identity thereto, or a multitude of polynucleotides comprising a multitude of sequence variants with as little as 70% identity to any fragment of SEQ ID NO:4, each of which

would retain promoter function. See claim 1, part (c). The claims are also broadly drawn to a multitude of transgenic plant cells and plants of any plant species which comprise constructs comprising said sequence fragments or sequence variants, wherein a heterologous coding sequence is expressed therefrom in amounts sufficient to confer an agronomic trait to said plant cells or plants. See claims 2-9.

In contrast, the specification only provides guidance for the isolation of a promoter from *Arabidopsis* comprising the entire SEQ ID NO:4, wherein said promoter functions to express heterologous coding sequences. No guidance is provided in which any particular fragment or particular variant of SEQ ID NO:4 would function as a promoter in the native plant species from which it was isolated, or in any other plant species into which it is introduced.

The Federal Circuit has recently clarified the application of the written description requirement. The court stated that a written description of an invention "requires a precise definition, such as by structure, formula, [or] chemical name, of the claimed subject matter sufficient to distinguish it from other materials." University of California v. Eli Lilly and Co., 119 F.3d 1559, 1568; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). The court also concluded that "naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material." Id. Further, the court held that to adequately describe a claimed genus, Patent Owner must describe a representative number of the species of the claimed genus, and that one of skill in the art should be able to "visualize or recognize the identity of the members of the genus." Id.

Finally, the court held:

A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus. Id.

See also MPEP section 2163, page 174 of chapter 2100 of the August 2005 version, column 1, bottom paragraph, where it is taught that

[T]he claimed invention as a whole may not be adequately described where an invention is described solely in terms of a method of its making coupled with its function and there is no described or art-recognized correlation or relationship between the structure of the invention and its function. A biomolecule sequence described only by a functional characteristic, without any known or disclosed correlation between that function and the structure of the sequence, normally is not a sufficient identifying characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence.

See also Amgen Inc. v. Chugai Pharmaceutical Co. Ltd., 18 USPQ 2d 1016 at 1021, (Fed. Cir. 1991) where it is taught that a gene (which includes a promoter) is not reduced to practice until the inventor can define it by "its physical or chemical properties" (e.g. a DNA sequence).

Given the claim breadth and lack of guidance as discussed above, the specification fails to provide an adequate written description of the genus of sequences as broadly claimed. Given the lack of written description of the claimed genus of sequences, any method of using them, such as transforming plant cells and plants therewith, and the resultant products including the claimed transformed plant cells and plants containing the genus of sequences, would also be inadequately described. Accordingly, one skilled in the art would not have recognized Applicant to have been in possession of the claimed invention at the time of filing. See the Written Description

Requirement guidelines published in Federal Register/ Vol. 66, No. 4/ Friday January 5, 2001/ Notices: pp. 1099-1111.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-10 and 12-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The use of the term "fragment" in claim 1 is not clearly defined in the specification with regard to any particular length, and as such fails to distinctly and particularly point out the subject matter of the invention that is being described (MPEP § 2105).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1 rejected under 35 U.S.C. 102(b) as being anticipated by Johnson-Hopson et al (GenBank accession AC005106).

The claim is drawn to a promoter comprising a polynucleotide sequence with 90-99% sequence identity to SEQ ID No:4 (see parts a and e of claim 1).

Johnson-Hopson et al. teach a polynucleotide sequence with 92.7% identity to the polynucleotide sequence of SEQ ID NO: 4. The ability of the sequence to function as a promoter would have been an inherent property.

Claims 1-10 and 12 rejected under 35 U.S.C. 102(b) as being anticipated by McElroy et al (US Patent 6,207,879).

The claims are drawn to a promoter comprising a fragment of SEQ ID NO:4 of any length, or a promoter exhibiting as low as 70% identity to a promoter comprising said fragment of SEQ ID NO:4 (see claim 1, parts a and b); constructs comprising said promoter operably linked to a 3' termination polynucleotide and a transcribable polynucleotide which is a selectable marker gene or which confers an agronomic trait including altered oil, protein, or micronutrient content; transgenic dicotyledonous plants including tobacco, tomato, potato, soybean, cotton, canola, sunflower and alfalfa; seeds and meal from said transgenic plants. The term "fragment" may reasonably be interpreted to include a single base pair.

McElroy et al. teach a transgenic dicotyledonous plant stably transformed with a construct comprising the maize RS81 promoter operably linked to a 3" transcription termination region and a polynucleotide which is a selectable marker gene (see e.g., claims 1-2, 10, 12-13, 16, 29 and 33). McElroy et al also teach a transgenic dicotyledonous plant stably transformed with the above construct wherein the polynucleotide confers an agronomic trait including altered oil, protein or micronutrient quality (see e.g., column 29, line 6 through column 30, line 30: column 30, line 62 through column 31, line 8). McElroy et al also teach the use of seeds and meal from

said transgenic plant (see e.g., column 65 line 37 through column 66, line 17; column 79, line 65 though column 80, line 18). McElroy et al also teach transgenic plants selected from the group consisting of tobacco, tomato, potato, soybean, cotton, canola, sunflower and alfalfa (see, e.g., claim 34). The maize RS81 promoter would inherently comprise a fragment of at least one base pair of SEQ ID NO:4 or any sequence with at least 70% identity thereto.

Claims 1-3, 5-7, 10, 12and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Debonte et al.

Claim 13 is drawn to a method of making vegetable oil and meal comprising extracting oil from the seed of a dicotyledonous, seed producing, oil containing plant comprising a plant promoter according to claim 1 operably linked to a transcribable polynucleotide molecule conferring altered oil content.

Debonte et al. teach a method of making vegetable oil and meal via incorporation of a promoter comprising a fragment of SEQ ID NO: 4, growing the dicotyledonous plant to produce seeds and extracting oil from the seed to produce extracted oil and meal (US patent 5850026 claim 14). Debonte et al. also teach a Brassica plant stably transformed with at least one recombinant nucleic acid construct comprising a regulatory sequence fragment operably linked to a wild-type microsomal delta-12 fatty acid desaturase coding sequence fragment conferring altered oil content in said plant, wherein the wild-type microsomal delta-12 fatty acid desaturase coding sequence fragment is a gene of agronomic interest (see claims 1 and 6). The regulatory promoter

would inherently comprise a fragment of at least one base pair of SEQ ID NO:4 or any sequence with at least 70% identity thereto.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brent Page whose telephone number is (514)-272-5914. The examiner can normally be reached on Monday-Friday 7-4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on (571)-272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Brent T Page

DAVID T. FOX
PRIMARY EXAMINER
GROUP 180 1638